

Summary of Risk Assessment Conducted Pursuant to subsection 83(1) of the *Canadian Environmental Protection Act, 1999*

New Substances Notification No. 18211: Silsesquioxanes, 3-[[3,5-dimethyl-heteromonocycle-1-yl]carbonyl]aminol propyl Pr, polymers with silicic acid (H₂SiO₄)tetra-Et ester, alkyl ether- and hydroxyl-terminated

Regulatory Decisions

Under the provisions for Substances and Activities New to Canada in Part 5 of the *Canadian Environmental Protection Act, 1999* (CEPA), and pursuant to section 83 of the Act, the Minister of the Environment and the Minister of Health have assessed information in respect of the substance, and have determined that it is not anticipated to enter the environment in a quantity or concentration or under conditions that have or may have an immediate or long term harmful effect on the environment or its biological diversity, constitute or may constitute a danger to the environment on which life depends, or constitute or may constitute a danger in Canada to human life or health.

Substance Identity

The notified polymer is silsesquioxanes, 3-[[3,5-dimethyl-heteromonocycle-1-yl]carbonyl]aminol propyl Pr, polymers with silicic acid (H₂SiO₄)tetra-Et ester, alkyl ether- and hydroxyl-terminated (Confidential Accession No. 19226-4). The substance does not meet the Reduced Regulatory Requirements criteria according to the New Substances Notification Regulations because it contains alkoxysilane and silanol groups.

Notified and Potential Activities

The substance is proposed to be manufactured in and/or imported into Canada in quantities greater than 10 000 kg/yr for use in automotive coatings. Potential uses are expected to be similar to those notified.

Environmental Fate and Behaviour

Based on its physical and chemical properties, if released to the environment, the substance will tend to partition to soil and sediment. The substance is expected to be persistent in soil and sediment because it reacts with water to form high molecular weight, insoluble complexes that are resistant to degradation. The substance is not expected to bioaccumulate based on its high molecular weight which will limit its ability to cross biological membranes.

Ecological Assessment

Based on the available hazard information on the substance and surrogate data on structurally related chemicals, the substance is expected to have low acute toxicity in aquatic invertebrates and algae (median effective loading and median effective concentration >100 mg/L) and low

chronic toxicity in algae (no-observed-effect concentration >10 mg/L). A predicted no-effect concentration was not calculated given the low potential for ecological hazard.

The notified and other potential activities in Canada were assessed to estimate the environmental exposure potential of the substance throughout its life cycle. Environmental exposure from the notified activity is expected to be low. Once cured the substance will be chemically reacted into coatings and unavailable for release, and any unreacted substance released to the environment is expected to be removed via wastewater treatment. Other potential uses in other industrial and consumer coatings will result in similarly low exposure. A predicted environmental concentration for notified and potential activities was not estimated given the low ecotoxicity and low potential for environmental exposure.

Based on its low ecotoxicity and its low potential for environmental exposure, the substance is unlikely to cause ecological harm in Canada.

Human Health Assessment

Based on the available hazard information, the substance has low potential for acute toxicity by the oral route of exposure (median lethal dose >2000 mg/kg body weight).

When the notified substance is used industrially in automotive paint, consumers may come into contact with end-use products containing the substance, however direct exposure is not expected because the substance will be chemically reacted into a stable matrix once the product is cured and will be unavailable for uptake. If the substance is used in other industrial or commercial coatings, the exposure to the general population is expected to be similarly low. Indirect exposure of the general population from environmental media such as drinking water is expected to be low.

Based on its low potential for exposure, the substance is not likely to pose a significant health risk to the general population, and is therefore unlikely to be harmful to human health.

Assessment Conclusion

When the substance is used as notified or for other potential uses, it is not suspected to be harmful to human health or the environment according to the criteria under section 64 of CEPA.

A conclusion under CEPA, on this substance, is not relevant to, nor does it preclude an assessment against the hazard criteria for Workplace Hazardous Materials Information System that are specified in the *Controlled Products Regulations* or *Hazardous Products Regulations* for products intended for the workplace.